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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/966,511 | 09/28/2001 | Deral T. Mosbey | 55837US002 | 4740 |

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| EXAMINER |
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YU, GINA C

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/966,511 | MOSBEY ET AL. | |
| | Examiner | Art Unit | |
| | Gina C. Yu | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 14, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 and 66-75 is/are pending in the application.
- 4a) Of the above claim(s) 53-61 and 71-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52, 66-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Amendment filed on October 14, 2003. Claims 1-61 and 66-75 are pending, of which claims 53-61 and 71-74 have been withdrawn from consideration. Claim rejections made under 35 U.S.C. § 112, second paragraph as indicated in the previous Office action dated July 14, 2003 are maintained in part and withdrawn in part in view of applicants' remarks as explained below. Claim rejections made under 35 U.S.C. § 103 (a) as indicated in the same Office action are modified to meet the new limitations of the amended claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 28, 29, 32, 36, 37, 38, 40, 41, 42, 48-52 are vague and indefinite because the metes and bounds of the limitation "sparingly soluble" are not ascertainable. While applicants assert that "sparingly soluble" is understood not to form transparent homogenous solution, examiner finds the argument unpersuasive because applicants' disclosure does not define to what measure of transparency or opacity the "sparingly soluble" polymer is required to meet the claimed limitation.

The remaining claims are rejected as depending on indefinite base claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-45, 48-52, 66-70 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Michaels (US 5389676) in view of Kernstock (US 4552685).

The instant invention is directed toward a water-in-oil emulsion comprising a vinyl polymer comprising ethylene oxide containing side chains and alkyl-Y-containing side chains, wherein Y is O or NR, wherein R is H or CH₃, and wherein the alkyl group of the alkyl Y containing side chain has at least 4 carbon atoms on average in a cyclic, branched, or straight chain configuration and optionally includes one or more heteroatoms, an oil phase, and a water phase, wherein the vinyl polymer is insoluble or sparingly soluble in the water phase.

Michaels teaches water-in-oil emulsions comprising amphoteric surfactants. Exemplified is an emulsion wherein the oil comprises 20% of the emulsion. As for instant claims 38-41, 50-52, 68, 70, the limitation "antimicrobial agent" and "pharmaceutical agent" are met because the surfactants used in the Michaels invention are taught to be anti-infective agents. See col. 3, line 9 – col. 4, line 30. The reference further teaches the application of the invention in pharmaceutical compositions such as wound healing and dressings. See col. 5, lines 30 – 37. Glycerine, ethylene glycol, propylene glycol and others, which are considered humectants, are taught as emulsion aids that increase viscosity and do not deactivate the anti-infective activity of the surfactants. Cellulose gums, glycerin, and gelatin are taught as co-emulsion aids that stabilize the emulsion. Hair and body shampoos are taught as preferred composition

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forms. Gel forms of the composition are additionally taught. The reference lacks vinyl polymers. See abstract; Col. 2, line 60-line 66; Col. 4, line 31-line 58. Col. 5, line 20-line 40; Col. 10, line 64-Col. 11, line 20.

Kernstock et al. teach thickened amphoteric surfactant solutions that are thickened by a polymer of 15-60% an alpha, beta-ethyleneically unsaturated carboxylic acid, such as methacrylic acid, 1-30% of a nonionic chain extender of an alpha beta-ethyleneically unsaturated monomer, such as ethyl acrylate, and 15-80% of a nonionic vinyl surfactant ester. See Col. 2 for monoethyleneically unsaturated poly(alkylene oxide) (meth)acrylic monomers of the instant invention and for alkyl (meth)acrylate monomers of the instant invention. The nonionic vinyl surfactant ester comprises ethylene oxide-containing side chains of isopropylene oxide groups and at least four ethylene oxide groups. The compositions are taught as useful as shampoos and is imparting a most desirable balance of viscosity and clarity properties to an amphoteric surfactant composition. The copolymer is taught as insoluble in an aqueous liquid.

The amount of copolymeric thickener most advantageously employed in preparing thickened amphoteric surfactant compositions will vary depending on the specific copolymer employed and the type and concentration of the amphoteric surfactant. Generally, the copolymers comprise from about 0.01 to about 10% of the composition. While the reference does not specifically state isooctyl acrylate, stearyl methacrylate, and polyethylene oxide, the reference does teach these monomers as possibilities. See Col. 2, line 1-Col. 3, line 15; Col. 4, line 11 –line 45. See Col. 6, line 64-Col. 8, line 30. See Col. 9, line 42-line 58.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the copolymers of Kernstock et al. to the composition of Michaels because of the expectation of achieving a shampoo that is effectively thickened while maintaining clarity.

Since Kernstock et al. teach acrylate vinyl polymers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify a vinyl polymer comprising isooctyl acrylate, stearyl methacrylate, and polyethylene oxide methacrylate because of the expectation of achieving a specific thickening property with a specific amphoteric surfactant. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See In re Aller, 105 USPQ 233. Thus discovering the optimum or workable monomer combinations with the combinations taught by Kernstock et al. would involve only routine skill.

The combination of references teaches the instant composition, thus the composition of the combined references must be stable substantive, and must have the property of providing a reducing in skin capacitance of greater than 15% and as having compatibility with various recited bioactive agents.

Claim 22 is not afforded patentable weight, as the future intended use of a composition claim is not given weight.

Since the vinyl polymer taught by Kernstock et al. is that same as that of the instant invention, the vinyl polymer of Kernstock et al. must have the same HLB values. The Examiner respectfully points out that the recitation of a moisturizing, tissue

antiseptic, personal care, and transdermal drug delivery is not given patentable weight; as a recitation of the intended utility in the preamble does not impart patentability to a known composition. In re Spada, 911 F.2d 105, 15 USPQ 2d 1655 (Fed. Cir. 1990).

2. Claims 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels in view of Kernstock et al. as applied to claims 1-45, 48-52 and 66-70 above, and further in view of Omura et al. (US 2003/0064046).

Michaels and Kernstock et al. are applied as discussed above. The references lack preferred make-up formulations.

Omura et al. teach cosmetic water-in-oil emulsions. Skin creams, hair creams, liquid foundation, eyeliner, mascara, eyeshadow, and other liquid emulsion or cream products, are taught in cosmetic forms of their water-in-oil emulsions. See (0032). It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of the combined references in the form of a make-up, as taught by Omura et al. because Omura et al. teach such water-in-oil composition forms as interchangeable and because of the expectation of achieving thickened, non-irritating mascara that increases the fullness of the lashes.

Response to Arguments

Applicant's arguments filed on October 14, 2003 have been fully considered but they are not persuasive.

Applicants argue that there is no motivation to combine the Michaels and Kernstock references allegedly because 1) Michaels show both O/W and W/O

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emulsions and 2) Kernstock fails to teach using the copolymeric thickener in an emulsion.

In response to applicants' remark that Michaels teaches both O/W and W/O emulsions, examiner respectfully notes that patents are relevant as a prior art for all they contain. It is well known in patent law that a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. See Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). In this case, the Michaels reference clearly teaches that both W/O and W/O emulsions are useful, old, and well known in the art. The reference even exemplifies W/O emulsions. Examiner asserts that the fact that the Michaels reference teaches an O/W emulsion should not be construed to mean that making an W/O emulsion is somehow nonobvious.

In response to applicants' assertion that there is no motivation to use the Kernstock copolymer in an emulsion because the prior art is used in an aqueous solution, examiner respectfully notes that it is well known in the emulsion art to incorporate water-soluble thickener in an aqueous phase prior to blending with the oil phase to make a W/O emulsion, as taught by Michaels. See Michaels Examples 16-23. In the previous Office action, the examiner had set forth the motivation to use the Kernstock copolymer in the Michaels invention, which is to effectively provide viscosity and clarity to the composition. Examiner views that there is nothing in the record to indicate any nonobviousness in incorporating the old and well-known water-soluble Kernstock copolymer in the aqueous phase of the Michaels composition.

Examiner withdraws the previous remarks that the claims 36, 37, 28, 40-42, 48-52, and 68-70 will be objected to under 37 C.F.R. 1.75 as being a substantial duplicate thereof. However, examiner respectfully points out that the stated future uses of the claimed compositions do not structurally limit the composition itself. No patentable weights are given to the recitation of mere intended use and purposes of the claimed invention. See MPEP § 2122.02.5

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

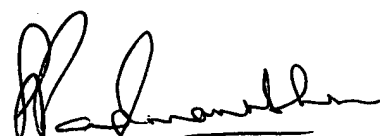
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

2/9/04